EXHIBIT E

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2327**
	2:12-md-02327
THIS DOCUMENT RELATES TO:	**HON. JOSEPH R. GOODWIN**
Lori Ludwig, et al. v. Ethicon, Inc.., et al	

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Bern Ripka Law Firm to give medical opinions related to Lori Ludwig. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae is attached to this report as **Ex. A**. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical and scientific certainty. My reliance list is attached as **Ex. B**.I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these devices. Further, I am familiar with non-mesh options for the

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treatment of stress urinary incontinence including autologous tissue based slings, biological graft-based slings, and periurethral bulking procedures. I have attended training provided by Ethicon, Inc. including training on TVT devices. Additionally, I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon a review of her medical records, and knowledge of her prior medical history.

Medical records reviewed include:

- Saint Mary's Medical Center
- Hartline and Shahbazi Ob/Gyn

Clinical History

- On October 4, 2000, Mrs. Ludwig (then Ms. Marshall as she was unmarried) saw Dr. Randal Hartline for an annual exam. At that time, complaints included deep dyspareunia (over the last two or three months preceding this visit) as well as severe menstrual cramping. Her past medical history was remarkable for hypertension, hypothyroidism, asthma, panic attacks and depression. Her surgical history was remarkable in part for a LEEP procedure performed by Dr. Hartline in 2003. She was G2P2. She also was having some stress urinary incontinence (SUI) as well as leakage during intercourse and

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while lying down at night. She was noted to be a 1 pack per day smoker. Physical exam was remarkable for a 2+ cystocele and a tender uterus. She was provided Detrol samples as well as Wellbutrin for smoking cessation and advised follow-up.

- On August 15th, 2003, Mrs. Ludwig saw Dr. Hartline for her annual exam. At that time, she had occasional dyspareunia and denied any SUI. Physical exam was unremarkable.

- On May 4, 2007, Mrs. Ludwig saw Dr. Hartline because of incontinence and heavy menstrual bleeding. Her incontinence occurred with sneezing but also when standing still. She would commonly wake up in bed to find herself lying in urine. Additional complaints included dyspareunia "most of the time". She had failed Detrol in the past and was prescribed Enablex.

- On May 31, 2007, Mrs. Ludwig presented to Dr. Hartline with complaints of spontaneous urine loss and urinary frequency along with heavy menstrual bleeding which worsened after she started taking Plavix. She had some improvement with nocturia.

- On November 13, 2007, Mrs. Ludwig underwent an anterior cervical discectomy and fusion of C4-5 and C5-6 secondary to herniated disc disease by Dr. Paul Johnson.

- On April 15, 2004, Mrs. Ludwig presented to Dr. Charles Reynolds with urinary incontinence.

- On May 20, 2008, Mrs. Ludwig underwent placement of a TVT-O sling by Dr. Charles Reynolds concurrently with a hysteroscopy and Thermachoice ablation by Dr. Randal Hartline. Dr. Reynolds placed the sling in a tension-free fashion, using a number 9 Hegar dilator as a spacer.

- On March 12, 2009, Mrs. Ludwig presented to Dr. Hartline with continuous severe menstrual cramping and spotting. She did well for a short period of time after the ablation. She had been having severe

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cramping for two months and had been spotting every other day. She complained of being unable to sleep because of the pain and also had minimal SUI. On physical exam, she was found to have a retroverted uterus.

- On March 23, 2009, Mrs. Ludwig, because of pelvic pain and continuous menstrual cramping, underwent a total abdominal hysterectomy and bilateral salpingo-oophorectomy by Dr. Hartline.

- On October 19, 2014, Mrs. Ludwig died from complications of lung cancer.

Methodology

My general opinions based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a

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given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk-benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

It is my opinion the IFU for the TVT in 2008 was not sufficient to enable informed consent from the patient. The TVT IFU provided:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction (i.e. too much tension) applied to the tape may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

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In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina, peri-vaginal, and those tissues adjacent to the mesh persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

The TVT IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event. These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. It is my opinion that a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events.

General Opinion No. 2

In 2008, alternative successful and safer sling procedures were available, including autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Mrs. Berry was unable to receive proper informed consent relating to this safer alternative because of the lack of information in the TVT IFU inherent to the risks of using synthetic mesh. As such, Dr. Reynolds was unable to warn Mrs. Ludwig of the subsequent complications she has suffered from.

Case Specific Opinion No. 1

Mrs. Ludwig's dyspareunia was caused by the TVT device. Recognized causes of dyspareunia following synthetic sling surgery include: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5) infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury; (7) lichen sclerosis; (8) vaginal tissue atrophy; and (9) pelvic floor dysfunction.

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Of interest, there is intermittent documentation of dyspareunia within the medical records. Additionally there are various references to pelvic and abdominal pain, although her pelvic pain ameliorated with Depo-Lupron therapy, suggesting a gynecological source of pain. Within Mrs. Ludwig's plaintiff fact sheet, however, there is clear reference to severe dyspareunia and abdominal pain that starts within two weeks following TVT surgery. She describes having constant lower abdominal pain (described as poking) as well as an inability to have intercourse without severe pain.

Regarding the differential diagnosis listed above, I am able to rule out erosion; paraurethral banding; infection and inflammation; lichen sclerosis; and vaginal tissue atrophy as potential causes of Mrs. Ludwig's vaginal pain and dyspareunia because I have not seen these findings documented. Moreover, up until 2009, she had no evidence nor reason to have vulvovaginal atrophy Additionally, I am not able to rule in neuromuscular injury or pelvic floor dysfunction as a causative factor having not seen this in the medical records either. The one plausible cause for Mrs. Ludwig's pelvic pain and dyspareunia, vaginal scarring with reduced elasticity, is also not seen within the medical records.

In summary, Mrs. Ludwig's post-TVT dyspareunia (which she attributes to her sling) has no clear etiology based on the current medical records I have reviewed. In as much as her plaintiff fact sheet puts forth these claims, the only way to corroborate and confirm these complaints would be to conduct or review an independent medical examination that might otherwise shed light on the etiology and underlying issues explaining her pelvic pain and dyspareunia. Unfortunately, givne her untimely death, this is not possible.

Case Specific Opinion No. 2

Ms. Ludwig's future prognosis as would have related to her pelvic pain and dyspareunia will never be known. Under the presumption that her dyspareunia and vaginal pain was caused by the TVT sling implanted in her by Dr. Reynolds, she would have continued to suffer from pelvic pain and dyspareunia. Even if she were to have all of her mesh removed, the surgery require to execute this procedure would have been extensive, complicated, and almost exclusively performed in tertiary academic centers. Moreover, I anticipate that if heroic surgery were to have been performed to remove all of her mesh that she would have developed further scarring and fibrosis inherent to this procedure.

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These represent my current opinions in this case. As any additional material becomes available, I reserve the right to modify or add to this opinion. Dated this the 22nd day of July, 2016

Sincerely,

Konstantin Walmsley, M.D.